

## REMARKS

Claim 25 has been amended to recite the language "eluting the nucleic acid from the solid phase." Support for these amendments can be found in the specification, e.g., at page 24, lines 9-12; page 78, line 24, to page 79, line 8; page 79, line 10, to page 80, line 7; and page 80, line 9, to page 81, line 6. The amendments add no new matter. Applicants have added no new claims. Claims 1-64 are under consideration.

### Rejection Under 35 U.S.C. § 112, Second Paragraph.

The Examiner rejects claims 1-24 and 41-63 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Office Action at page 2, section 2. Specifically, the Examiner stated that claims 1, 3, 4, and 41 are vague and indefinite for recitation of the term "substantially." *Id.*

The term "substantially" in claims 1, 3, 4, and 41 is used in the phrases "substantially neutralizing the cationic surfactant" or in the phrase "substantially neutralizes the cationic surfactant." Applicants respectfully assert that the phrase "substantially neutralizing" a cationic surfactant is specifically defined, for example, in the specification at pages 20-21, paragraphs 62 and 63. The specification states that "the term 'substantially neutralizing' the cationic surfactant, for the purposes of this application, means that more nucleic acid in a sample is capable of binding a solid phase application with such substantial neutralization than without the neutralization."

Specification, page 20, lines 12-16.

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The Examiner states that this argument is not convincing because "it is unclear of what exactly is 'more nucleic acid' ...," and that "there is no comparison to something else that define[s] the term more." *Id.*

The sentence at page 20, lines 12-16, of the specification, however, clearly includes a comparison. The sentence states that "'substantially neutralizing' the cationic surfactant, for the purposes of this application, means that **more** nucleic acid in a sample is capable of binding a solid phase application with such substantial neutralization **than without the neutralization.**" (Emphasis added).

The comparison is between (1) the amount of nucleic acid capable of binding a solid phase with substantial neutralization of a cationic detergent and (2) the amount of nucleic acid capable of binding a solid phase without neutralization of a cationic detergent. The meaning of the sentence at page 20, lines 12-16, is quite clear to one skilled in the art.

Thus, the term "substantially" is defined with respect to claims 1, 3, 4, and 41. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

#### Rejection Under 35 U.S.C. § 102(e)

The Examiner rejects claims 1-6, 9, 10, 14-17, 22-27, 30-33, and 38-40 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Pat. No. 6,242,188 to Dattagupta et al., ("Dattagupta"). Office Action at pages 3, section 4.

In the Office Action mailed June 25, 2002, the Examiner stated that Dattagupta "describes compositions and methods for releasing nucleic acids from cells in a form

that is suitable for labeling/capture, amplification, or detection in a single reagent addition step" and which include "a lipid, membrane fluidizing compound, enzyme for degrading cell structure, metal chelators, or one or more nucleic acid probes or primers complementary to the nucleic acid to be detected." Office Action mailed June 25, 2002, page 3, section 4.

Applicants respectfully traverse the rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002) (citations omitted); see Manual of Patent Examining Procedure § 2131 (8<sup>th</sup> ed. 2001) ("MPEP") ("to anticipate a claim, the reference must teach every element of the claim").

Claims 1 and 25 of the present application recite methods for obtaining nucleic acids from a biological sample that comprise binding the nucleic acid to a solid phase. Claims 2-6, 9, 10, 14-17, and 22-24 ultimately depend from claim 1. Claims 26-27, 30-33, and 38-40 ultimately depend from claim 25.

Applicants assert that the Examiner failed to state that Dattagupta teaches a method for obtaining nucleic acid from a biological sample that comprises binding the nucleic acid to a solid phase.

The Examiner contends that this argument is not convincing because Dattagupta states that the "nucleic acid probe can be used in any conventional hybridization technique. As improvements are made and conceptually new formats are developed, such can be readily applied to the present probes. Conventional hybridization formats

that are particularly useful include those wherein the sample nucleic acids or the polynucleotide probe are immobilized on a solid support (solid-phase hybridization) and those wherein the polynucleotide species are all in solution (solution hybridization).”

Office Action, page 4, section 6, citing Dattagupta, col. 15, lines 43-51.

Applicants respectfully assert that the part of Dattagupta cited by the Examiner refers to a method of detecting nucleic acid sequences, not a method of obtaining nucleic acids from a biological sample. Dattagupta teaches the detection of nucleotide sequences by hybridization where nucleic acids that have been isolated from a sample are immobilized on a solid support. The immobilization on a solid support is for detection purposes. Dattagupta does not teach obtaining nucleic acids from a biological sample comprising binding the nucleic acids to a solid phase.

Further, claim 1 recites a method of obtaining nucleic acids from a biological sample comprising substantially neutralizing a cationic surfactant. The Examiner has not stated or established that Dattagupta teaches obtaining nucleic acids from a biological sample comprising substantially neutralizing a cationic surfactant.

Without acquiescing to the rejection, and solely to expedite prosecution, claim 25 has been amended to further recite “eluting the nucleic acid from the solid phase.” The Examiner has not stated or established that Dattagupta teaches obtaining nucleic acids from a biological sample comprising eluting the nucleic acid from the solid phase.

For at least the reasons stated above, claims 1-40 are not anticipated by Dattagupta under 35 U.S.C. §102. Reconsideration and withdrawal of the §102 rejection is respectfully requested.

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Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-40 under 35 U.S.C. § 103(a) as allegedly being obvious over Dattagupta in view of U.S. Pat. No. 5,130,423 to Van Ness et al. ("Van Ness"). Office Action, pages 3 to 4, section 6.

As discussed above, claims 1 and 25 recite in part a method for obtaining nucleic acids from a biological sample comprising binding the nucleic acid to a solid phase. Dependent claims 2-24 and 26-40 ultimately depend from claims 1 and 25 respectively, and thus include all of the elements of claims 1 and 25 respectively. As discussed above, the Examiner failed to establish that Dattagupta teaches a method for obtaining nucleic acids from a biological sample comprising binding the nucleic acid to a solid phase. The Examiner fails to assert, let alone establish, that Dattagupta would have suggested such a method. Further, Van Ness does not teach and would not have suggested a method for obtaining nucleic acids comprising binding the nucleic acid to a solid phase.

As discussed above, claim 1 recites in part a method for obtaining nucleic acids from a biological sample comprising substantially neutralizing the cationic surfactant. Dependent claims 2-24 ultimately depend from claim 1, and thus include all of the elements of claim 1. As discussed above, the Examiner failed to establish that Dattagupta teaches a method for obtaining nucleic acids from a biological sample comprising substantially neutralizing the cationic surfactant. The Examiner fails to assert, let alone establish, that Dattagupta would have suggested such a method. Further, Van Ness does not teach and would not have suggested a method for obtaining nucleic acids comprising substantially neutralizing the cationic surfactant.

As discussed above, claim 25 recites in part a method for obtaining nucleic acids from a biological sample comprising eluting the nucleic acid from the solid phase. Dependent claims 26-40 ultimately depend from claim 25, and thus include all of the elements of claim 25. As discussed above, Dattagupta teaches a method for obtaining nucleic acids from a biological sample comprising eluting the nucleic acid from the solid phase. Dattagupta would not have suggested such a method. Further, Van Ness does not teach and would not have suggested a method for obtaining nucleic acids comprising eluting the nucleic acid from the solid phase.

Thus, the Examiner has failed to establish that the combination of Dattagupta and Van Ness would have rendered obvious any of claims 1-40.

Applicants respectfully request reconsideration and withdrawal of the § 103 rejections of claims 1-40 in view of Dattagupta and Van Ness.

#### Conclusion

Applicants respectfully assert that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, Applicants request that the Examiner call the undersigned ((650) 849-6676) to arrange an interview prior to taking action.

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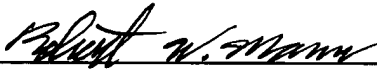
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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By:   
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